



PATENT  
Customer No. 22,852  
Attorney Docket No. 6832.0016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
Craig A. ROSEN et al. ) Group Art Unit: 1653  
Application No.: 09/833,041 ) Examiner: Hope A. Robinson  
Filed: April 12, 2001 )  
For: ALBUMIN FUSION PROTEINS )

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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Sir:

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RESPONSE TO RESTRICTION REQUIREMENT

In a restriction requirement dated August 4, 2003, the Examiner required restriction under 35 U.S.C. § 121 between:

- Group I: Claims 1-21 drawn to an albumin fusion protein comprising a therapeutic protein X (SEQ ID NO:) and albumin (SEQ ID NO: 18), classified in class 424, subclass 192.1;
- Group II: Claims 22-25, drawn to a method of treating a disease or disorder in a patient, classified in class 514, subclass 12;
- Group III: Claim 26, drawn to a method of extending the shelf life of Therapeutic protein X (SEQ ID NO:), classified in class 435, subclass 449; and
- Group IV: Claims 27-29, drawn to a nucleic acid molecule, classified in class 536, subclass 23.4.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

Applicants provisionally elect to prosecute Group I, claims 1-21 drawn to an albumin fusion protein comprising a therapeutic protein X (SEQ ID NO:) and albumin (SEQ ID NO: 18), with traverse.

According to MPEP § 803, there are two requirements that must be met before a proper restriction requirement may be made: (1) the inventions must be independent or distinct as claimed; and (2) there must be a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that the Office has failed to establish the second requirement set forth in MPEP § 803, that a serious burden exists on the Examiner if restriction is not required between the Groups of claims.

In the present invention, Group I is directed to an albumin fusion protein comprising a therapeutic protein X and albumin. Group II is directed to a method of treating a disease or disorder comprising the step of administering the albumin fusion protein as defined in Group I. Additionally, Group IV is directed to a nucleic acid molecule encoding the albumin fusion protein as defined in Group I. A search and examination of the subject matter of Group I would encompass a search for the subject matters of Groups II and IV, and any additional search would not impose a serious burden upon the Examiner.

It is therefore respectfully requested that the restriction requirement be reconsidered. In the event that the restriction requirement is maintained, Applicants reserve the right to file divisional applications on the non-elected inventions and/or to request rejoinder of appropriate claims once the subject matter of claims 1-21 is found allowable.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

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Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)

Please grant any extensions of time required to enter this response and charge  
any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

By: Charles E. Van Horn  
Charles E. Van Horn  
Reg. No. 40,266

Dated: August 15, 2003

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
[www.finnegan.com](http://www.finnegan.com)